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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/585,985

07/13/2006

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1712

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7590

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EXAMINER

YAKOVLEVA, GALINA M

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/585,985	<b>Applicant(s)</b> KOHNO ET AL.	
	<b>Examiner</b> GALINA YAKOVLEVA	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10/19/2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 12-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The examiner charged with the present case has changed. See contact information below. Responsive to communications entered 10/19/2010.

#### ***Status of Claims***

Claims 1-34 are pending. Claims 12-34 are withdrawn. Claims 1-11 are examined.

#### ***Priority***

The instant application, 10/585,985, Pub. No. US 2008/0227118 A1, is a 371 filing of PCT/JP2005/000737 filed on January 21, 2005, which claims foreign priority to PCT/JP2004/000504 filed on January 21, 2004.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-11 are rejected under 35 U.S.C. 102(b)** as being anticipated by **Nishibu et al.** "Quantitative filtration-blotting of protein in the presence of sodium dodecyl sulfate and its use for protein assay," 2003, *Analytical Biochemistry*, 319, pp. 88-95 (IDS entered 08/28/2008).

The claims, as recited in independent Claim 1, are drawn to a method for immobilizing a protein to a solid-phase, comprising filtrating the protein with the solid-

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phase having hydrophobic surface in the presence of a lower alcohol and a halogenocarboxylic acid.

**Nishibu** *et al.*, throughout the publication, and, for example, at page 89, left column second paragraph through the right column, third paragraph, teach a method of filtration-blotting proteins onto a polyvinylidene difluoride (PVDF) membrane, comprising the steps of (1) mixing a protein solution with varying ethanol, trichloroacetic acid (TCA) and sodium dodecyl sulfate (SDS) concentrations, which read on the concentrations recited in the instant dependent claims, to produce a sample and (2) placing the sample in a vacuum pump attached to a PVDF membrane, thereby allowing the protein to become immobilized onto the membrane.

Therefore, each and every element of the claims are met by the Nishibu *et al.* reference.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1-11 are rejected under 35 U.S.C. 103(a)** as being unpatentable over **Cheley et al.** "Assaying Nanogram Amounts of Dilute Protein," *BioTechniques*, 1991, vol. 10, No. 6, pp. 731-732 (IDS entered 07/22/2008), in view of **Jacobson et al.**, "Important parameters in semi-dry electrophoretic transfer;" *Electrophoresis*, 1990, 11, pp. 46-52 (IDS entered 07/13/2006).

**Cheley et al.**, throughout the publication, and, for example, at page 731, right column, third paragraph, teach a method of immobilizing protein samples using a solution of 0.267% SDS (calculated by the examiner based on the provided concentration/dilution) and 15% TCA (calculated by the examiner based on the provided concentration/dilution) to a nitrocellulose membrane using a dot blotter.

**Cheley et al.** teach neither a lower alcohol nor a hydrophobic membrane.

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**Jacobson** *et al.*, throughout the publication, and, for example, at page 47, left column, first paragraph, teach an electrophoretic transfer method that uses a transfer buffer comprising methanol and SDS to transfer proteins from a gel to various types of membranes. At page 47, right column, second paragraph; page 49, right column, first paragraph; Jacobson *et al.* teach that methanol improves protein binding efficiency. At page 47, right column, third paragraph, Jacobson *et al.* teach the use of a hydrophobic membrane, such as PVDF. At page 50, right column, first paragraph, Jacobson *et al.* teach that the PVDF membrane provides high mechanical strength which exhibits sensitivity advantages compared to other existing membranes when colloidal gold and India Ink are used for staining the proteins. At page 47, left column, first paragraph, Jacobson teaches the use of 20% methanol and 0.1% SDS.

It would have been *prima facie* obvious, at the time the invention was made, for one of ordinary skill in the art to use a PVDF membrane and methanol, taught by Jacobson *et al.*, for immobilizing protein samples by a method taught by Cheley *et al.*

One of ordinary skill in the art, at the time the invention was made, would have been motivated to use a PVDF membrane and methanol, taught by Jacobson *et al.*, for immobilizing protein samples by a method taught by Cheley *et al.*, because it would be desirable, to use a PDVF membrane that provides high mechanical strength for specific labeling techniques and methanol that increases the likelihood of protein binding, as taught by Jacobson *et al.*

One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for using a PVDF membrane and methanol,

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taught by Jacobson *et al.*, for immobilizing protein samples by a method taught by Cheley *et al.* because the use of PVDF membranes and methanol for immobilizing protein samples are known in the art.

Although the TCA concentration, taught by Cheley *et al.*, and the methanol concentration, taught by Jacobson *et al.*, are outside of the claimed concentration ranges, one of ordinary skill in the art would have found it obvious to modify Cheley's TCA and Jacobson's methanol teachings by optimizing the concentrations of the compounds to arrive at the claimed ranges:

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). MPEP 2144.05.

### ***Response to Arguments***

#### **I. Rejection of Claims 1-11 under 35 U.S.C. 102(b)**

On February 12, 2010, Applicant has submitted a certified English translation of PCT/JP2004/000504.

On October 19, 2010, Applicant has filed a petition under 37 CFR 1.78(a)(3) to accept an unintentionally delayed priority claim for the instant application to claim benefit under 35 U.S.C. § 119 and 35 U.S.C. § 120 of two international applications: PCT/JP2004/000504 filed on January 21, 2004 and PCT/JP2005/000737 filed on January 21, 2005, both of which designate the United States. In the reply filed 10/19/2010, Applicant argues that since the effective US application date of

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PCT/JP2004/000504 is the international filing date of January 21, 2004, and this date is within one year of the **Nishibu** *et al.* reference (August 1, 2003), the rejection under 35 U.S.C. 102(b) does not apply.

This argument is not persuasive for the following reasons.

Per a decision mailed to Applicant on 02/28/2011, the petition has been dismissed. Here, the instant application, filed July 13, 2006, is a national stage application of PCT/JP05/00737, filed January 21, 2005, which claims foreign priority to PCT/JP2004/000504, filed January 21, 2004. For purposes of section 102(b), the U.S. filing date is January 21, 2005. Since the Nishibu *et al.* reference was published in 2003, it qualifies as a 102(b) reference against the instant claims.

The rejection of Claims 1-11 under 35 U.S.C. 102(b) as being anticipated by Nishibu *et al.* is maintained.

## II. **Rejection of Claims 1-11 under 35 U.S.C. 103(a)**

Applicant traverses the rejection on the grounds that “because Jacobson indicates that SDS is not preferable for binding in nitrocellulose, the skilled artisan would not have motivation to modify Cheley's method with Jacobson.” This argument is not persuasive because the skilled artisan would clearly appreciate the benefit of using a PDVF membrane that provides high mechanical strength for specific labeling techniques and methanol that increases the likelihood of protein binding, taught by Jacobson *et al.*, in a dot blotting assay taught by Cheley *et al.*

The rejection of Claims 1-11 under 35 U.S.C. 103(a) is therefore maintained.



***Conclusion***

Claims 1-11 are rejected.

**THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GALINA YAKOVLEVA whose telephone number is (571)270-3282. The examiner can normally be reached on Monday-Friday 8:00 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571)272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G. Y./

Examiner, Art Unit 1641

/Mark L. Shibuya/

Supervisory Patent Examiner, Art Unit 1641